

PATENT

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Examiner: Wiest, Philip R.

Applicant(s): MEDOW et al.

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Title: **MEDICAL SHUNT/VALVE FOR REGULATION OF BODILY FLUIDS**

**REQUEST FOR RECONSIDERATION OF
REQUIREMENT FOR RESTRICTION
(37 CFR §1.143)**

Mail Stop Amendment

Commissioner for Patents

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In Response to the Office Action of November 4, 2008, reconsideration of the restriction requirement is requested in light of the following comments.

1. Summary of Restriction Requirement

The Office Action contends that the inventions claimed in the following groups are patentably distinct and require restriction to a single group:

Group I: The apparatus of claims 1-6, 8-21 and 73-75, allegedly classified in class 604, subclass 9 (class definition: Surgery | Devices transferring fluids from within one area of body to another (e.g., shunts, etc.) | With flow control means (e.g., check valves, hydrocephalus pumps, etc.)).

I certify that this paper is being electronically submitted to the U.S. Patent and Trademark Office via the EFS-Web online filing system on the following date:

1 December 2008

Date of Electronic Submission

Marcus Layton

Signature

Group II: The apparatus of claims 22-25, 27-37, 76 and 77, allegedly classified in class 604, subclass 32 (class definition: Surgery | Means for introducing or removing material from body for therapeutic purposes (e.g., medicating, irrigating, aspirating, etc.) | Material introduced into and removed from body through passage in body inserted means | Flow control | Rotary valve).

Group III: The apparatus of claims 38, 39, 41-49 and 52-57, allegedly classified in class 604, subclass 30 (class definition: Surgery | Means for introducing or removing material from body for therapeutic purposes (e.g., medicating, irrigating, aspirating, etc.) | Material introduced into and removed from body through passage in body inserted means | Flow control).

Group IV: The apparatus of claims 58 and 60-71, allegedly classified in class 604, subclass 9 (class definition: Surgery | Devices transferring fluids from within one area of body to another (e.g., shunts, etc.) | With flow control means (e.g., check valves, hydrocephalus pumps, etc.)).

2. Provisional Election of Group (37 CFR §1.143)

Group I (claims 1-6, 8-21 and 73-75) is provisionally elected for further examination. Despite this provisional election, it is requested that the restriction requirement be withdrawn for the reasons set out below in Section 3.

3. Traverse

Two conditions must both be met before a proper requirement for restriction can be made (MPEP 803):

- (1) The inventions must be independent or distinct as claimed; *and*
- (2) There must be a serious burden on the Examiner if restriction is not required.

As discussed below in sections 3.a and 3.b, it is submitted that neither condition is met for any of Groups I-IV with respect to any other Group.

3.a. First Criterion for Restriction: Serious Burden on the Examiner

As discussed by MPEP 803 and 808.02, a *prima facie* showing of a serious burden on the Examiner may be established by the Examiner's showing of a different field of search, separate classification, or separate status in the art. With respect to separate classification or separate status in the art, it is important to note that these do not automatically provide evidence of a serious burden; rather, they only do so where they demonstrate that a different field of search is indeed present (MPEP 808.02).

What constitutes a "different field of search" is defined in MPEP 808.02 and MPEP 904-904.03. MPEP 808.02 states that a different field of search exists "where it is necessary to search for one of the inventions in a manner that is not likely to result in finding art pertinent to the other invention(s)." MPEP 904-904.03 then provide guidelines for the field of the search to be performed prior to examination of an application. It is noted that the art must be searched with respect to variant embodiments (MPEP 904.01(a)), patentable equivalents (MPEP 904.01(b)), and analogous art (MPEP 904.01(c)). MPEP 904.02 further notes that the Examiner's field of search should "cover the claimed subject matter and should also cover the disclosed features which might reasonably be expected to be claimed" (as does MPEP 904.02(a)), and MPEP 904.03 states that the search must be "commensurate with the limitations appearing in the most detailed claims in the case."

It is evident from the principles set forth in the aforementioned sections of the MPEP that **there is no different field of search for any Group with respect to any other Group, and that no serious burden to the Examiner would arise if all claims are searched and examined.**

Regarding Groups I and IV, it should be apparent that if independent claim 1 and its dependent claim 17 are searched (as required by the foregoing MPEP sections if Group I is elected), the salient limitations of Group IV must be searched as well:

- The Office Action states that Group IV is "drawn to a body fluid shunt having a piston wherein the location of the piston is independent of the pressure in the downstream side of the fluid passage, classified in class 604, subclass 9."
- However, claim 1 recites a piston, and (for example) its dependent claim 17 then recites "The body fluid shunt of claim 1 wherein the position of the piston is independent of the

pressure in the downstream side of the fluid passage.” At least claims 1 and 17 of Group I therefore encompass the matter to which the Office Action states Group IV is drawn. Further, as the Office Action acknowledges, both of Groups I and IV are “classified in class 604, subclass 9.” Thus, there is clearly no serious burden if Group IV is searched and examined as well as Group I.

Regarding Groups I and II, if independent claim 1 and its dependent claims 2 and 5 are searched (as required by the foregoing MPEP sections if Group I is elected), the salient limitations of Group II must be searched as well:

- The Office Action states that Group II is “drawn to a body fluid shunt having a valve defined as a cutout within a movable valve actuating member, classified in class 604, subclass 32.” Note that claim 25 then more specifically recites that “the valve actuating member is a piston.”
- However, claim 1 recites a body fluid shunt having a valve “wherein the valve is at least partially defined by a drain port,” and a piston “having a cutout defined therein, the cutout being alignable with the drain port when the piston is displaced.” At least claim 1 of Group I therefore encompasses the matter to which the Office Action states Group II is drawn.

In similar respects, ***regarding Groups I and III***, if independent claim 1 and its dependent claims 2 and 5 are searched (as required by the foregoing MPEP sections if Group I is elected), the salient limitations of Group III must be searched as well:

- The Office Action states that Group III is “drawn to a body fluid shunt comprising a valve that is confined to move along a travel axis, wherein fluid flowing between the upstream and downstream ends of the fluid passage when the valve is open flows through the valve along a valve flow direction oriented at least substantially perpendicular to the travel axis, classified in class 604, subclass 30.”
- However, claim 1 recites a body fluid shunt having a valve, and (for example) its dependent claim 5 then recites that “the piston is displaceable along a piston travel axis; and . . . fluid flowing through the valve between the upstream and downstream sides of the flow passage flows along a valve flow direction oriented at least substantially

perpendicular to the piston travel axis.” At least claims 1 and 5 of Group I therefore encompass the matter to which the Office Action states Group III is drawn.

Additionally, please consider: *review of at least the independent claims of each Group illustrates that the alleged classifications for Groups I and IV (class 604, subclass 9) also apply to Groups II and III as well.* To illustrate, note that U.S. Patent 5,643,195 to *Drevet* – which was used on the last Office Action in anticipation rejections of *all groups* – is classified in class 604, subclass 9, illustrating that the various groups plainly *do not* have a different field of search.¹

Because the Examiner's *prima facie* showing of a serious search burden has been rebutted, it is submitted that the requirement for restriction should be withdrawn. As noted by MPEP 803, if the search and examination of an application can be made without serious burden, the Examiner must examine the application on the merits even if it includes claims to distinct or independent inventions.

3.b. Second Criterion for Restriction: Distinct or Independent Inventions

The Office Action contends that the inventions of Groups I-IV are unrelated (i.e., independent). As noted in MPEP 806.06, “Inventions as claimed are independent if there is no disclosed relationship between the inventions, that is, they are unconnected in design, operation, and effect.”

This is plainly incorrect. Compare the independent claims of each group (claim 1 for Group I, claim 22 for Group II, claim 38 for Group III, and claim 58 for Group IV) versus the device of, for example, FIG. 1: *these claims all cover the device of FIG. 1.* The Groups are therefore all plainly related.

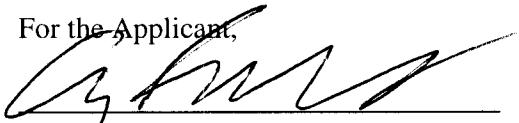
¹ Similarly, the alleged classifications for Group II (class 604, subclass 32) and Group III (class 604, subclass 30) also apply to each of the other groups as well. Also note that the alleged classification for Group II (class 604, subclass 32) is indented under the alleged subclass for Group III (class 604, subclass 30). *How can one search Group II without also searching the salient matter of Group III?*

4. In Closing

If any questions regarding the application arise, please contact the undersigned attorney. Telephone calls related to this application are welcomed and encouraged. In this respect, it is noted that the Office Action states that a telephone call was made to the undersigned attorney on 10/29/08. However, no call or voicemail was received by the undersigned attorney. If a voicemail message is left, the undersigned attorney will act to promptly return the call.

The Commissioner is authorized to charge any fees or credit any overpayments relating to this application to deposit account number 18-2055.

For the Applicant,



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